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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,767	10/17/2006	Lene Moller	13323-105002	9900

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

NOTIFICATION DATE	DELIVERY MODE
12/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,767	MOLLER, LENE	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14,16-26,32,34 and 50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14,16-26,32,34 and 50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/10/09; 05/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received September 10, 2009.

Applicants' arguments filed have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 10-13, 15, 27-31, 33, 35-49 are canceled. Claims 1-9, 14, 16-26, 32, 34, 50-61 are currently under examination.

Priority: The request for priority to provisional applications 60/546972, filed February 24, 2004, and 60/540005, filed January 30, 2004, is acknowledged.

Objections and Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, 16-26, 32, 50-51, 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 32 have been amended to recite a hemostatic composition comprising dry gelatin powder and hyaluronic acid, said composition having a mean particle size in the range of 30-250 μm. The specification (p. 6 lines 24-39 to 7 lines 1-15) discloses that it is the particle

size of the gelatin powder that is 30-250 μm, and not the composition comprising dry gelatin powder and hyaluronic acid. Therefore, while there appears to be support for a composition comprising said dry gelatin powder, wherein said gelatin powder has a particle size of 30-250 μm, and hyaluronic acid (p. 8-10), there does not appear to be support for a composition comprising dry gelatin powder and hyaluronic acid, where said composition has a particle size of 30-250 μm.

Claims 2-9, 14, 16-26, 50-51, 60 are included in this rejection because they are dependent on claims 1 and 32.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 14, 16-22, 25-26, 50-51, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08, previously cited) in view of Yamamoto et al. (US 20010008636) in view of Silver et al. (US 5196185; previously cited). Ferdman et al. disclose an apparatus for containing a chamber storing a composition comprising gelatin or collagen powder (abstract, col. 3 lines 6-25; claim 1, 25-26). Ferdman et al. disclose a variety of hemostatic agents can be used with the apparatus, including collagen powder and/or gelatin powder, where said hemostatic agent has a density of 0.016 to 0.064 g/cm^3 (col. 3 lines 15-20; claim 16-17, 50). As noted in Figure 2, the apparatus has a source chamber (28) for containing the gelatin powder (col. 3 lines 29-30; claim 6-7). The apparatus is a spraying device

which is hand-held and is activated by a hand-pushed button (col. 4 lines 17-24; claim 4-5, 60). The hemostatic agent is dispersed through the outlet conduit (80) and onto living tissue, wherein the outlet conduit has a diameter of about 0.5 cm (col. 5 lines 1-5, col. 6 lines 15-20; claim 2). From Figure 3, the outlet conduit (80) has an elongate tip (Fig. 3; claim 3). Ferdman et al. do not teach hyaluronic acid or that said gelatin powder has a mean particle size, i.e. of 30 to 250 μm.

Yamamoto et al. disclose collagen and gelatin are biopolymers that are used in tissue repair (p. 2 [0015]). Yamamoto et al. disclose gelatin/hyaluronic microcapsules (p. 4 example 2). Yamamoto et al. do not explicitly teach a particle size of 30 to 250 μm.

Silver et al. disclose a composition of collagen powder having a particle size of from 0.1 to 50 μm (col. 4 lines 15-21). Silver et al. disclose that hyaluronic acid can be added to said composition in order to promote tissue ingrowth (col. 3 lines 56-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ferdman et al. by adding hyaluronic acid to said gelatin powder in order to make gelatin/hyaluronic microcapsules with a particle size of 0.1 to 50 μm, as suggested by Yamamoto et al. and Silver et al., in order to make a hemostatic composition to be stored in the powder delivery system of Ferdman et al. (1-7, 14, 16-17, 25-26, 50, 60). The motivation to do so is given by Silver et al. which disclose that said hyaluronic acid can promote tissue ingrowth and Yamamoto et al., which disclose that said hyaluronic acid can be used with gelatin to make microcapsules. Regarding the motivation to use the particle size of 0.1 to 50 μm of Silver et al., it would be reasonable for one of ordinary skill to use that size in the manufacture of gelatin/hyaluronic microcapsules since Silver et al. disclose said size is successful in the treatment of wounds. Further, since Ferdman et al. disclose that gelatin powder can be used in

an apparatus for treating tissue, it would be reasonable for one of ordinary skill to know that any suitable gelatin particle composition that can be used to treat wounds, in powder or particle form, can be successfully incorporated into said apparatus of Ferdman et al. since the healing properties of the gelatin powder would be the same.

Regarding the moisture content limitation that is recited in claims 16, 50, it should be noted that Ferdman et al. disclose gelatin powder; therefore, it would be reasonable for one of ordinary skill to conclude that the powder, by its natural properties, would be dry and have no moisture content.

In addition to dried gelatin, Ferdman et al. also disclose polysaccharide and cellulose are appropriate hemostatic agents (col. 3 lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the teachings of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. as noted above by adding an agent which improves the adhesive properties of the collagen powder, i.e. starch, glucose, etc. (claims 18-22, 51). As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art." In this instance, Ferdman et al. disclose that polysaccharide is a hemostatic agent; therefore, it would be reasonable for one of ordinary skill to recognize that (poly)saccharides are hemostatic agents that can be combined with another known hemostatic agent to form a third composition.

While Ferdman et al. may not disclose the (poly)saccharide improves the adhesive properties of a collagen powder composition, it should be noted that "[I]t is not necessary in order to establish a prima facie case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant"); In re Lintner, 458 F.2d 1013, 1018, 173 USPQ 560, 562 (CCPA 1972) ("The fact that [applicant] uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references."). In this instance, the saccharide is being incorporated as a hemostatic agent with a known hemostatic agent, i.e. collagen powder, in order to arrive at a third composition comprising hemostatic agents.

Regarding the concentration of said agent recited in claim 22, it should be noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). In this instance, it would be reasonable for one of ordinary skill to determine at which concentration of polysaccharide would yield the optimum hemostatic composition for wound treatment.

In their remarks, Applicants assert that the claims have been amended to require a dry powder comprising gelatin and hyaluronic acid in a particle size in the range of 30-250 μm. Neither Ferman et al. nor Silver et al. teach compositions of hemostatic powder comprising gelatin and hyaluronic acid. Therefore, one of ordinary skill would not arrive at the presently claimed elements which require at least a dry powder comprising gelatin and hyaluronic acid in a particle size in the range of 30-250 μm. Applicant's arguments have been fully considered but they are not persuasive.

Reply: As noted above, the Yamamoto et al. reference is a newly cited 103(a) reference that discloses gelatin/hyaluronic microcapsules. Claims 1-7, 14, 16-22, 25-26, 50-51, 60 are rejected under 103(a) for the reasons noted above.

Claims 8-9, 34, 52-59, 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08, previously cited) in view of Yamamoto et al. (US 20010008636) in view of Silver et al. (US 5196185; previously cited) in view of knowledge in the art. The teachings of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. are outlined above. Ferdman et al. do not explicitly disclose an attachment to the nozzle of the powder delivery system.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to know that the nozzle of the powder delivery system comprising a hemostatic composition of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. can be modified with different types of attachments, i.e. a protective structure with different designs,

(claims 8-9, 34, 53-59, 61). A general search of the prior art reveals powder delivery systems with different types of nozzles and structural extensions; therefore, it would be reasonable for one of ordinary skill to know that said nozzle of Ferdman et al. can be fitted with a protective structure that has an appropriate design.

Ferdman et al. and Yamamoto et al. also disclose that hemostatic agents can include dried collagen and dried gelatin (col. 3 lines 10-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the teachings of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. as noted above by adding collagen powder to the gelatin powder in said hemostatic composition (claim 52). As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art." In this instance, both Ferdman et al. and Yamamoto et al. disclose that dried gelatin and collagen powder are hemostatic agents; therefore, it would be reasonable for one of ordinary skill to combine two hemostatic agents in order to produce a third composition.

In their remarks, Applicants assert that claim 34 recites a protective structure. The sliding valve gate of Ferdman et al. is not equivalent to a protective structure. Rather, the sliding valve gate of Ferdman et al. is used for operating the embodiment showed in Figure 5 to

successively open or close gas inlets. Applicant's arguments have been fully considered but they are not persuasive.

Reply: One of ordinary skill would know that the nozzle of a delivery system is similar to the outlet of a vacuum cleaner and that various attachments and/or structures with different designs can be attached depending on the purpose that is being used.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08, previously cited) in view of Yamamoto et al. (US 20010008636) in view of Silver et al. (US 5196185; previously cited). The teachings of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. are outlined above. Silver et al. further disclose a method of wound treatment comprising applying to a wound, the collagen powder composition in the form of an aerosol (col. 6 lines 30-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a wound by spraying the hemostatic composition of Ferman et al. in view of Yamamoto et al. in view of Silver et al. (claim 32). The motivation to do is given by Silver et al. which disclose that hemostatic compositions in particle form can be sprayed onto a wound.

The reasons for maintaining the 103(a) rejection of claim 32 is the same as noted above, i.e. the Yamamoto et al. reference is a newly cited 103(a) reference that discloses gelatin/hyaluronic acid microcapsules.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (US 5951531; IDS 02.15.08, previously cited) in view of Yamamoto et al. (US 20010008636) in view of Silver et al. (US 5196185, previously cited), as evidenced by Epstein et al. (US 6045570; IDS 02.15.08, previously cited). The teachings of Ferdman et al. in view of Yamamoto et al. in view of Silver et al. are outlined above. Yamamoto et al. disclose thrombin microspheres can be used as an adhesive and/or biological sealant.

The Epstein et al. reference is used as evidence that thrombin can be mixed with collagen powder in order to form a biological sealant composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Ferdman et al. in view Yamamoto et al. in view of Silver et al. by adding the thrombin to said hemostatic composition comprising gelatin/hyaluronic particles (claims 23-24). The motivation to do so is given by Yamamoto et al., which disclose thrombin can be successfully made into microspheres to be used as an adhesive, and as evidenced by Epstein et al., which disclose that the addition of thrombin to collagen powder can form a biological sealant; therefore, it would be reasonable for one of ordinary skill to know that treating a wound with a biological sealant would improve healing of the wound.

The reasons for maintaining the 103(a) rejection of claims 23-24 is the same as noted above, i.e. the Yamamoto et al. reference is a newly cited 103(a) reference that discloses gelatin/hyaluronic acid microcapsules.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

December 10, 2009

Marsha Tsay
Art Unit 1656